UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/800,070 | 03/06/2001 | Yves Delmotte | WM-252.00 | 4142 |

7590 12/19/2003

Baxter Healthcare Corporation
P.O. Box 15210
Irvine, CA 92614

| EXAMINER | |
|---|---|
| GHALI, ISIS A D | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1615 | |

DATE MAILED: 12/19/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/800,070 | DELMOTTE, YVES | |
| | Examiner | Art Unit | |
| | Isis Ghali | 1615 | |

*-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 June 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *37-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

The receipt is acknowledged of applicant's request for RCE and amendment B, both filed 06/30/2003.

Claims 37-84 are pending and included in the prosecution.

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/30/2003 has been entered.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 37-84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment of the claims to recite "self-supporting fibrin material" has introduced new matter. Recourse to the specification revealed no disclosure of the self-support fibrin material anywhere.

### *Double Patenting*

4. Claim 69 objected to under 37 CFR 1.75 as being a substantial duplicate of claim 58, because both claims recite the firbrinogen containing material that forms the first component. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### *Claim Rejections - 35 USC § 112*

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 40, 58, 69, and 84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 40, the claim is confusing as it recites "two densities". Recourse to the specification revealed that the two different densities are obtained by having two

surfaces, page 4, paragraph 0024, or by orientation of the fibers of the biopolymer, and non of these conditions are clear from the claim language. Clarification is requested.

Regarding claims 58 and 69, the claims recite fibrin as a member of the first component of claim 57 that can be converted into fibrin. Clarification is requested.

Claim 84 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: using the elements of claim 37 in the steps of making the article of claim 84.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 37-39, 44-46, 48-50, 56-58, 62-69, 70-84 rejected under 35 U.S.C. 102(b) as being anticipated by Dinh, US 5,510,077 ('077).

US '077 disclosed porous antithrombic fibrin stent that is longitudinally stretched reads on claims 37-39 (abstract, col.3, lines 6-9; col.8, lines 21-23). The fibrin is in the form of fibril and forms tube having internal diameter of 2.7 to 3.4 mm, reads on claim 44, 48-50, 78, and 79 (col.3, line 1, col.10, lines 47-49). The fibrin is cross-linked, claim 56 (col.3, lines 5-63). The reference disclosed a method of making the stent comprising generating the fibrin gel from fibrinogen by the action of thrombin, and longitudinally

stretching the stent, reads on claims 57, 58, and 69 (col.3, lines 55-65; col.4, lines 1-7; col.8, lines 20-23, 33-54; col.9, lines 65-67; col.10, lines 1-2). The process of making above included the step of drying and dehydration, claims 62 and 68 (col.10, line 59). The composition is molded into a stent and stretched mechanically using pressure or balloon, that stretch the tube in two directions, and the composition is lyophilized, claims 63-67, 77, 80 and 81, 84 (col.10, lines 12-65). The concentration of fibrinogen in the composition is 26 mg/ml and thrombin is present in an amount of 1-120 IU/ml, claims 70-74 (col.5, lines 3-6; col.10, lines 1-3). The composition comprising calcium and drugs, such anticoagulant or anti-inflammatory, etc., claim 75 and 76 (col.4, lines 7-10, 29; col.5, lines 11-16; col.6, lines 3-15). The composition comprises water that is removed from the composition, claim 68, 82-83 (col.4, lines 40-55). The reference disclosure reads on the self-supported fibrin material because composition having the same ingredients will inherently have the same functional properties.

### *Claim Rejections - 35 USC § 103*

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 37-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '077.

The reference teaches the porous fibrin stent made of fibrinogen by the process of the instant claims.

The reference does not teach the different densities and the degree of the difference between the densities, claims 40-43. However, the claimed densities are not considered critical, absent evidence to the contrary. One having ordinary skill in the art would have achieved the claimed densities based on the motivation of providing different thickness, different degree of mechanical properties and biostability of the device.

The reference dos not teach diameter of the 100-2500 micrometer, claims 47, 51, or the wall thickness of claims 52 and 53. However, the claimed diameter of 2500 is not considered patentable over the prior are diameter of 2.7 (2700 micrometer), absent evidence to the contrary. It is obvious to one having ordinary skill in the art to select the thickness of the tube, as well as the diameter, based upon the blood vessel where the stent would be inserted and the strength of the blood flow in this vessel.

The reference does not teach the amount of fibrin, claim 55. However, the amount of fibrin does not impart patentability to the claims, absent evidence to the contrary. It is expected to have the same amount of fibrin in the composition of the prior art that has the same amounts of the starting material and the converting material as in the instant claims.

The reference does not teach the degree of stretching of the length, claim 59-61. The degree of stretching does not impart patentability to the claims, absent evidence to the contrary. However, the reference disclosed that fibrin is fragile and the expansion

should be controlled to obtain the stent with proper dimensions for expansion in vivo without tearing.

Thus, it would have been obvious to one having ordinary skill in the art a the time of the invention to deliver a fibrin material that is stretched longitudinally as disclosed by the reference, and adjust the densities, diameters and the thickness of the wall, and the degree of stretching of the material according to particular site of application, motivated by the teaching of the reference that fibrin is fragile and the expansion should be controlled to obtain the a material with proper dimensions for expansion in vivo without tearing, with reasonable expectation of having an elongated fibrin structure that is useful for vascular and wound treatment.

***Response to Arguments***

11. Applicant's arguments filed 6/30/2003 have been fully considered but they are not persuasive.

The main gist of applicant argument against the 102 and 103 rejection of the claims over US '077 is that the fibrin material disclosed by the reference is not self-supported, and the reference disclosed metal stent as a supporting member.

In response to the above argument, the examiner position is that the reference disclosed a fibrin stent having the same composition and produced by the same process as claimed by the applicant, and this will provide a material having the same functional properties, such as self-supported. The specification does not provide any support or disclosure of the self-supported material. However, the reference disclosed

the step of lyophilization of the product, and applicant discloses that lyophilization of the product will provide dry porous support, in page 15, paragraph 70, of the specification. Note that a comprising-type language does not exclude other elements or materials, and permits the presence of the metal support. *Cues Inc. vs. Polymer Industries*, USPQ 2d 1847 (DC ND GA 1988).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615

Isis Ghali

ISIS GHALI
PATENT EXAMINER